

period followed by a 10-week, randomized, double-blind, placebo-controlled period. A total of 170 patients were randomized to receive a physician-determined dose of botulinum toxin type A (BoNT-A) or placebo. Functional disability was measured by patients and physicians using a scale from 0 (no functional disability) to 4 (very severe disability). Functional disability was measured at study visits at weeks 2, 4, 6, 8, and 10 of the randomized, double-blind period of the study. **RESULTS:** The baseline mean physician-assessed functional disability scores were 1.87 for botulinum toxin and 1.88 for placebo. The mean change in physician-assessed functional disability showed a greater reduction in the BoNT-A group compared with the placebo group at all timepoints, with the difference being significant at weeks 4, 6, and 8 ($P \leq 0.029$). A higher proportion of patients had a decrease of one grade or more in physician-assessed functional disability in the BoNT-A group at all time periods. The baseline mean patient-assessed functional disability scores were 1.95 in the BoNT-A group and 1.78 in the placebo group. A greater reduction in the mean change of patient-assessed functional disability was seen with BoNT-A compared with placebo at all timepoints. The patient-assessed functional disability between the two groups was significantly different at weeks 2, 6, 8, and 10 ($P \leq 0.008$). A one grade or greater reduction in patient-assessed functional disability was experienced by a higher proportion of botulinum toxin patients at all timepoints compared with placebo. Rates of adverse events were nearly equivalent between groups (59.1% BoNT-A vs. 58.5% placebo group). **CONCLUSION:** Treatment with BoNT-A showed significant and sustained improvements in functional disability when assessed by both the physician and the patient.

PND40

PHYSICAL AND PATIENT REPORTED OUTCOMES IN MULTIPLE SCLEROSIS

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OBJECTIVE: Most Multiple Sclerosis (MS) clinical trials focus on relapses and MRI measures of disease activity. Disease outcome measures in clinical trials and practice focus on physical outcomes and, in particular, the ambulation oriented Expanded Disability Severity Scale (EDSS). This study evaluated the relationships between various physical and patient reported outcomes (PROs) in MS patients. **METHODS:** Charts were abstracted for 98 MS patients in a single MS center that captured both physician-evaluated outcomes and PROs. This study reports the last available evaluation. Spearman rank correlations and a recursive partitioning algorithm were used to evaluate relationships between five physical (box/blocks, 9-hole peg, timed walk, Tinetti balance, and EDSS) and 3 PRO (modified fatigue impact scale, Beck depression inventory, and Espworth sleepiness scale) measures in addition to standard demographic and disease characterizing variables. **RESULTS:** The rank correlation between the box/blocks and nine-hole peg tests (standard tests for fine motor control) was 0.9 ($p < 0.001$) while the rank correlation between box/blocks and timed walk was 0.71 ($p < 0.001$). Moderate correlations were observed for the PROs: fatigue and depression was 0.57 ($p < 0.001$); fatigue and sleepiness was 0.52 ($p < 0.001$); and depression and sleepiness was 0.39 ($p < 0.001$). No significant correlations were observed between either depression or sleepiness and any physical outcome measure. Fatigue was correlated with 9-hole peg (0.41, $p = 0.023$), timed walk (0.44, $p = 0.014$), and EDSS (0.34, $p = 0.013$). The recursive partitioning algorithm found the stron-

gest physical outcome associated with fatigue to be EDSS and the best split was at EDSS \leq ("minimal" versus "mild" disability). **CONCLUSION:** Moderate correlations were found within the physical outcome measures and within PROs; but the relationship between physical outcomes and PROs was weak. Because most clinical trials and evaluating neurologists focus on physical measures in MS, it is likely that much of the disease impact is being missed.

PND41

PHYSICIAN AND PATIENT REPORTED OUTCOMES REVEAL RAPID ONSET OF IMPROVEMENT AND OVERALL CONVENIENCE, TOLERABILITY AND EASE-OF-USE WITH RASAGILINE IN PARKINSON'S DISEASE (PD) IN LEGATO

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OBJECTIVE: To evaluate investigator and patient-reported satisfaction and ease-of-use of Azilect(r) (rasagiline tablets) in community neurological practices. Rasagiline is a potent, once daily, novel, irreversible MAO-B inhibitor approved for PD as initial monotherapy or adjunct therapy. Pivotal trials showed improvement in the Unified Parkinson's Disease Rating Scale for monotherapy and reduced OFF time for adjunct therapy. Other measures of patient- and investigator-reported outcomes may be important such as ease-of-use and patient satisfaction. **METHODS:** LEGATO is an open-label study of once-daily rasagiline 0.5 mg and 1 mg in PD patients at 38 community-based centers. Baseline treatment determined patients' stratification to adjunct or monotherapy. Evaluations were at weeks 1, 2, 4, and 12. Endpoints included: patient and investigator reported Clinical Global Improvement (CGI) score; investigator and patient-reported change from baseline in Schwab & England Activities of Daily (ADL) score; and investigator and patient-reported satisfaction/ease-of-use ratings. **RESULTS:** A total of 272 patients were enrolled: 123 monotherapy patients and 149 adjunct patients with 245 completers. At all visits, investigator reported CGI was significantly improved for both mono and adjunct therapy ($p < 0.001$). At all visits, patient reported CGI was also significantly improved for both mono and adjunct therapy ($p < 0.001$). Patient-reported CGI was similar to Investigators', although maximal improvement occurred later for patients. Median satisfaction/ease-of-use scores were 9 for monotherapy (range 6 to 30 with 6 being best) and 10 for adjunct therapy (range of 8 to 40 with 8 being best) for both patients and investigators. Investigators noted statistically significant improvement in ADL of 3 points at the end of 12 weeks, whereas patients did not note changes from baseline. **CONCLUSION:** Both investigators and patients noted significant effectiveness beginning at week one as measured by CGI, found rasagiline convenient and easy to use, and were satisfied with the dosing frequency and tolerability of once-daily rasagiline.

PND42

THE DEVELOPMENT OF A PATIENT SATISFACTION INSTRUMENT FOR INSOMNIA: A PSYCHOMETRIC APPROACH

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OBJECTIVE: The purpose of this study was to develop an instrument to assess treatment satisfaction for patients with insomnia. **METHODS:** Specific patient satisfaction items were identified from the existing literature by an expert panel of physicians,

researchers, and clinicians. Two focus groups containing eight to ten patients who met the inclusion criteria for insomnia (diagnosis, history) were surveyed. A preliminary instrument containing 42 items (scale: 1 = not important at all to 5 = extremely important), including demographic characteristics and co-morbidities, was developed and then pretested in 14 additional patients prior to validation testing. **RESULTS:** Currently, 109 patients have participated in the testing of the instrument (mean age 50 + 11.5 years, 67.9% female). Principal components exploratory factor analysis (KMO = 0.85) reduced the instrument to 17 items (Cronbach α = 0.90) in 5 domains. Cronbach α for the 5 domains (contentment, dosing flexibility, outlook, value, and treatment satisfaction) ranged from 0.73 to 0.86. Convergent and discriminant validity were assessed to determine scale acceptability for further analysis. Goodness of fit measures for the measurement model (AMOS, version 7) were $\chi^2 = 50.8$, $df = 53$, $p = 0.559$; CFI = 1.00, GFI = 0.94, NFI = 0.92, RMSEA = 0.001, which support the relationship between the data and the hypothesized model. We anticipate recruiting more patients to ensure that the data are consistent. **CONCLUSION:** Preliminary data from the structural equation model revealed a 17-item instrument with 5 important domains (contentment with therapy, dosing flexibility, and outlook with respect to treatment satisfaction and value). Further assessment and validation of the instrument is planned. This novel instrument may provide greater knowledge regarding the impact of psychological domains on treatment satisfaction for patients with insomnia.

PND43

LEVEL OF SATISFACTION OF SPANISH MULTIPLE SCLEROSIS PATIENTS TREATED WITH A NEW FORMULATION OF AVONEX® (INTERFERON BETA-1A 30 MCG INTRAMUSCULAR, ONCE WEEKLY, SOLUTION FOR INJECTION READY TO USE)

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OBJECTIVE: Multiple sclerosis (MS) is a chronic neurodegenerative disease which is the second most frequent cause of neurological disability in young adults. The relapsing forms of the disease are primarily treated with interferon beta or glatiramer acetate. The aim of this study was to evaluate the level of satisfaction of Spanish MS patients treated with the new formulation of Avonex®, and whether this influences adherence. **METHODS:** Data were obtained from the Global Adherence Project, a multicenter open-label, post-marketing surveillance study, performed in 17 centers in Spain. This included assessment of the level of patient and neurologist satisfaction with the new Avonex® formulation after 6 months of therapy. Two questionnaires were administered, one for patients and another for neurologists. The study was approved by ethics committees and patients signed informed consent. Descriptive statistical analyses were performed. **RESULTS:** Of 257 patients included, 57 (22.2%) were treated with Avonex®; 55.4% of patients and 5.9% of neurologists were fully satisfied with the new formulation. Most neurologists (88.3%) had intermediate satisfaction scores. For patients and for neurologists, the most noteworthy aspect of the change of formulation was the ease of use (73.2% and 82.4%, respectively), followed by ease of storage (44.6% and 29.4%), ease of injection (39.3% and 70.6%), less medication administered (25.0% and 11.8%) and for patients only, better tolerability (8.9%). Adherence with Avonex® was 96.4%, the highest among the therapies evaluated. **CONCLUSION:** Both patients and neurologists were satisfied with Avonex® as solution for injection. The most noteworthy aspect was the ease of use. This seems to have a positive influence in the overall patients' adherence to the therapy.

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PND44

CANADIAN PATIENT SURVEY TO ASSESS PATIENTS' PLIGHT TO DYSTONIA DIAGNOSES AND BOTULINUM TOXIN TYPE A TREATMENT

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OBJECTIVE: Assess the types and number of health care professionals seen by patients before diagnosis with dystonia and the length of time from onset of symptoms. Describe the common types of dystonias that are treated by the movement disorder specialists and when appropriate, receive Botulinum Toxin Type A treatment. **METHODS:** Patients with dystonia were asked to complete a 19-question survey developed by the Canadian Movement Disorders Survey Group. Questions included patient demographics, length of time from onset, number and types of physicians seen, other diagnoses made, number treated with Botulinum Toxin Type A and distance traveled. **RESULTS:** In this interim analysis, 550 patients with dystonia were surveyed. Majority of the patients were female (71%), traveling an average of 99 km one-way. Most common dystonia diagnoses were cervical dystonia (51%), hemifacial spasm (20%), and blepharospasm (11%). Common diagnoses made prior to the dystonia diagnoses were nerve/muscle problem (34%), stress/psychological problem (39%), tremor (20%), fibromyalgia (19%), TMJ (16%), joint/tendon problem (15%) and spine (11%). The average number of physicians seen before the dystonia diagnosis was 3.2. Amongst these were family physician (78%), neurologist (78%), movement disorder specialist (29%), chiropractor (18%), eye care doctor (17%), neurosurgeon (11%), and physiotherapist (15%). Most physicians who made the dystonia diagnosis were neurologist (69%) and movement disorder specialist (27%). The average time in years from onset of symptoms to dystonia diagnosis were: cervical dystonia 5.2 (n = 278), blepharospasm 3.5 (n = 60), spasmodic dysphonia 4.0 (n = 10), limb dystonia 1.2 (n = 17), Meige syndrome 2.6 (n = 14), hemifacial spasm 3.2 (n = 112), generalized dystonia 8.0 (n = 8), oromandibular dystonia 5.0 (n = 8). 94% of patients were treated with Botulinum Toxin Type A following their diagnosis with dystonia. **CONCLUSION:** The number of physicians seen and length of time from onset to dystonia diagnosis is substantial. Increased awareness of dystonia at the primary care level may improve these rates.

PND45

USE OF DISEASE-MODIFYING DRUGS IN MULTIPLE SCLEROSIS: A POPULATION BASED STUDY

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OBJECTIVE: Highly expensive disease modifying agents (DMAs) were introduced in the 1990s to reduce the frequency of relapse and to slow disease progression in patients with multiple sclerosis (MS). However, the patterns of DMAs use remain largely unknown. This study examines data from 2001–2005 population-based survey of MS patients to estimate duration of DMA use and switching behavior, controlling for patient risk factors. **METHODS:** We examined patterns of DMA use of 670 patients with relapsing remitting (RR) and secondary progressive (SP) MS from the Sonya Slifka Longitudinal Multiple Sclerosis Study. We generated Kaplan Meier covariate-adjusted estimates